Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No. 10-6108 (ES)(JAD)

(Filed Electronically)

Oral Argument Requested

JAZZ'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO BIFURCATE CLAIMS RELATING TO THE '730 PATENT FAMILY

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I. INTRODUCTION

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") submits this memorandum in support of its motion to bifurcate and stay claims related to the '730 patent family. Those patents claim methods of safely using and administering certain prescription drugs prone to abuse, misuse, and/or diversion. The claims of the '730 patent family cover Jazz's Risk Evaluation and Mitigation Strategy ("REMS") associated with the use of Jazz's XYREM® product.

Proceeding with those claims now will thus result in a substantial misuse of the Court's and the parties' resources

II. STATEMENT OF FACTS

Jazz makes and sells XYREM®—the only FDA-approved treatment for cataplexy (sudden loss of muscle tone) and excessive daytime sleepiness in patients with the sleep disorder narcolepsy. The active ingredient in XYREM® is sodium oxybate, the sodium salt of gamma-hydroxybutyrate or "GHB." While useful for treating patients with narcolepsy, GHB has a notorious past based on its abuse as a recreational drug and its association with drug-facilitated

¹ The '730 patent family includes U.S. Patent Nos. 7,668,730, 7,765,106, 7,765,107 and 7,895,059. The remaining patents-in-suit are U.S. Patent Nos. 6,472,431, 6,780,889, 7,262,219, 7,851,506, 8,263,650, and 8,324,275 (collectively, "the '431 patent family").

sexual assaults.² As a result of its past abuse, the FDA required a restricted distribution system for XYREM[®] as a condition of marketing the drug.³ The FDA will similarly not approve a generic version of XYREM[®] without an acceptable REMS system. See 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii).

Thus, to obtain FDA approval to market its proposed ANDA product, Roxane must propose and receive FDA approval of a REMS for its product. *See* 21 U.S.C. § 355-1(i)(1). Roxane must either use the same REMS as XYREM[®], or certify to the FDA that: (1) the burden of using the same REMS outweighs the benefits; or (2) parts of the XYREM[®] REMS are patented (or trade secrets) and Roxane has been unable to obtain a license. *See* 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii). Even if the FDA waives the shared REMS requirement, a separate REMS must be "comparable" to the approved REMS. *Id*.

² See Drug Enforcement Administration, WHO Questionnaire For Review of Dependence-Producing Psychoactive Substances by the 32nd Expert Committee on Drug Dependence, May 17, 2000, at Sec. 2.2.1-2.2.3, available at http://www.fda.gov/ohrms/dockets/dailys/00/may00/053000/c000003.pdf (last visited December 3, 2013).

Today, such pharmaceutical restricted distribution systems are referred to as "REMS." XYREM® was included on the list of products deemed by the FDA to have in effect an approved REMS under 21 U.S.C. § 355-1. See 73 Fed. Reg. 16314 (Mar. 27, 2008).

[&]quot;Ex. __" refers to the Declaration of Gabriel P. Brier, submitted herewith.

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Alternatively, trial on the oth	er patents-in-
suit may resolve all issues between the parties. As such, Jazz respectfully requests to	that the Court
bifurcate and stay claims related to the '730 patent family	

III. ARGUMENT

A. <u>Legal Standards</u>

Fed. R. Civ. P. 42(b) states that, "[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims." Fed. R. Civ. P. 42(b). The decision to bifurcate is within the Court's "broad discretion," and is made on a "case-by-case basis." *Ricoh Co. v. Katun Corp.*, No. 03-2612, 2005 WL 6965048, at *1 (D.N.J. Jul. 14, 2005) (granting motion to bifurcate); *see also Barr Lab., Inc. v. Abbott Lab.*, 978 F.2d 98, 115 (3d Cir. 1992) (affirming bifurcation). Due to their complexity, patent cases are routinely bifurcated to promote efficiency and simplify issues. 8 MOORE's FEDERAL PRACTICE 3D § 42.24[3], at n.5; *Ricoh*, 2005 WL 6965048, at *1 ("In the context of patent cases, experienced judges use bifurcation and trifurcation both to simplify the issues [] and to maintain manageability") (quotation omitted); *see also Wyeth v. Abbott Labs.*, No. 08-230 2010 WL 4553545, at *2 (D.N.J. Nov. 3, 2010) (granting motion to bifurcate in case involving multiple patents and multiple accused products).

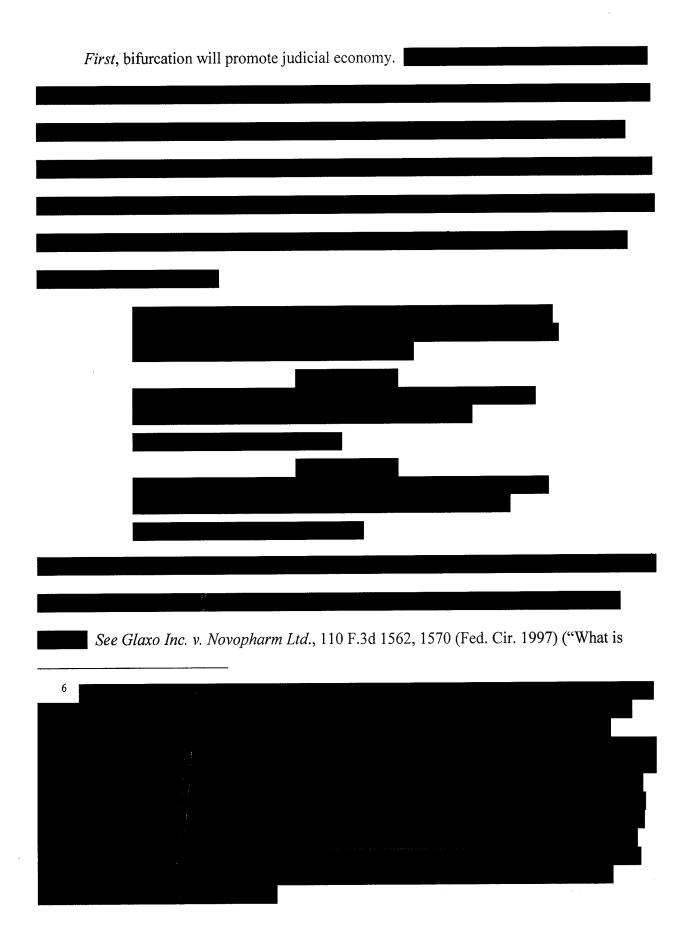
B. Bifurcation Will Promote Judicial Economy and Reduce the Risk of Prejudice

Jazz requests bifurcation of trial on all claims related to the '730 patent family, as well as a stay of expert discovery on those claims

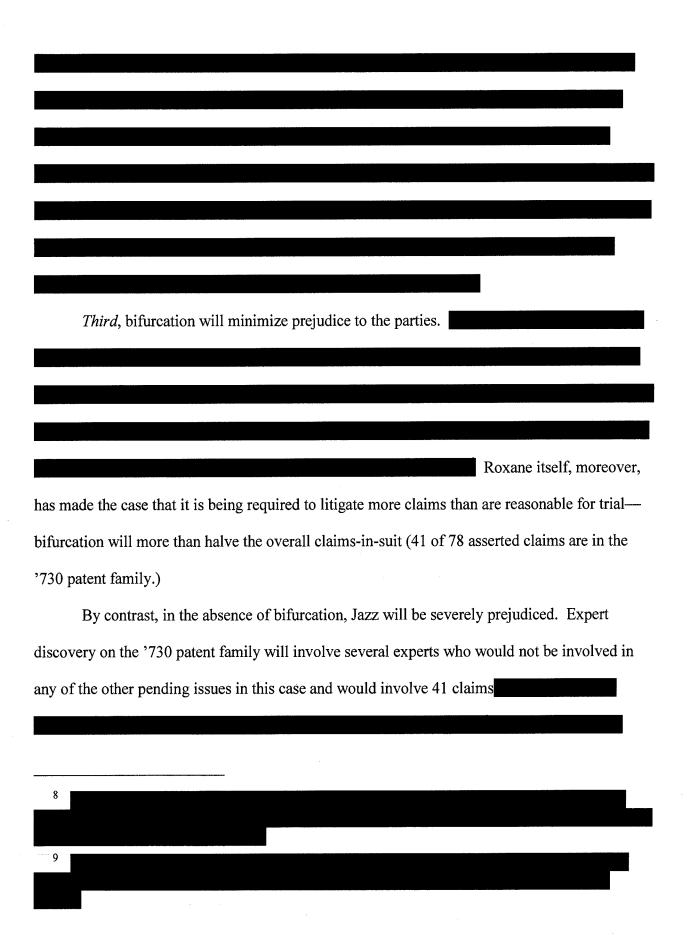
Under the current circumstances, Rule 42

strongly favors bifurcation.⁵

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ely to be sold, or p	referably, what wil	ll be sold, will ulti	mately determine	whether infringeme
sts.").				
				See Hines or
half of Sevier v. Se	cretary of HHS, 94	0 F.2d 1518, 1522	2 (Fed. Cir. 1991)	(Article III of the
S. Constitution "ha	as been interpreted	as barring federal	courts from rende	ering advisory
	tna Life Ins. Co. v.			
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Finally, the same reasons that support bifurcation also support staying expert discovery on the '730 patent family claims. *See Akzona Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 232 (D. Del. 1984) ("It is implicit in [Federal Rule] 42(b) that a trial judge who grants bifurcation has the power to limit discovery to issues relevant to the first trial."). ¹⁰

IV. CONCLUSION

For the reasons stated above, Jazz respectfully requests that the Court grant its motion to bifurcate claims relating to the REMS patents.

Respectfully submitted,

Dated: December 3, 2013

By: s/ Charles M. Lizza

Charles M. Lizza William C. Baton SAUL EWING LLP

One Riverfront Plaza, Suite 1520

Newark, NJ 07102-5426

(973) 286-6700 clizza@saul.com

The factual issues underlying the claims pertaining to the '730 patent family are also separate and distinct from those underlying the remaining patents-in-suit, which are directed to formulations and methods of treating narcolepsy patients, not REMS.

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Gabriel P. Brier
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Richard G. Greco RICHARD G. GRECO PC 90 State Street, Suite 700 Albany, New York 12207 (212) 203-7625

Attorneys for Plaintiff Jazz Pharmaceuticals, Inc.